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Howmedica
OSTEONICS

Howmedica Osteonics'
TRIATHLON® TOTAL KNEE IFU
TRIATHLON® REVISION INSERT X3® COMPONENTS

Howmedica Osteonics Corp.
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A subsidiary of Stryker Corporation

EC REP

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QIN4443_AUS_ Rev. AA

Refer to product label for CE Mark Status and Legal Manufacturer.
The CE mark is only valid if also found on the product label.

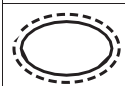
Labelling Symbols Glossary

The following is a list of symbols that may be used on Stryker medical device labeling. Refer to individual product labels for applicable symbology for each product.

Symbol	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.1.1
	Authorized Representative in the European Community	Indicates the Authorized representative in the European Community.	ISO 15223-1	5.1.2
	Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1	5.1.3
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1	5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1	5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1	5.1.6
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1	5.1.7
	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.	ISO 15223-1	5.2.2

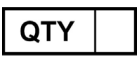
Symbol	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1	5.2.3
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1	5.2.4
	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1	5.2.6
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	ISO 15223-1	5.2.7
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.	ISO 15223-1	5.2.8
	Keep away from sunlight	Indicates a medical device that needs protection from light sources.	ISO 15223-1	5.3.2
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 15223-1	5.3.4
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1	5.3.7
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1	5.4.2

Symbol	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1	5.4.3
 https://www.stryker.com/au/en/about/our-locations/australia/ifus/additional.html	Consult instructions for use	Indicates an instruction to consult an electronic instructions for use (eIFU). This symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer's eIFU website or any other appropriate indication on the use of eIFU. The indicator may be placed either alongside, beneath or surrounding the symbol.	ISO 15223-1	5.4.3.A.16
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1	5.4.4
	MR conditional	Indicates an item with demonstrated safety in the MR environment within defined conditions.	ASTM F2503	N.A
	MR safe	Indicates an item that poses no known hazards resulting from exposure to any MR environment.	ASTM F2503	N.A
	MR unsafe	Indicates an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503	N.A

Symbol	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
	Prescription only	Requires prescription for sale in the United States and is used in place of the statement below: Caution: Federal law restricts this device to sale by or on the order of a physician, dentist, or licensed practitioner.	21 CFR Part 801.109	N.A
	Medical Device	Indicates the item is a medical device	ISO 15223-1	5.7.7
	Double sterile barrier system	Indicates two sterile barrier systems	ISO 15223-1	5.2.12
	Single sterile barrier system	Indicates a single sterile barrier system	ISO 15223-1	5.2.11
	Single sterile barrier system with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside	ISO 15223-1	5.2.13
	Single sterile barrier system with protective packaging outside	Indicates a single sterile barrier system with protective packaging outside	ISO 15223-1	5.2.14
	Unique Device Identifier	Indicates a carrier that contains Unique Device Identifier information.	ISO 15223-1	5.7.10
	Contains hazardous substances	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine-disrupting properties	ISO 15223-1	5.4.10

Symbol	Title of Symbol	Description of Symbol	Standard/Law Reference	Clause
	Patient identification	Indicates the identification data of the patient	ISO 15223-1	5.7.3
	Date (of Implantation)	To identify the date that information was entered, or a medical procedure took place	ISO 15223-1	5.7.6
	Health care center or doctor	To indicate the address of the health care center or doctor where medical information about the patient may be found	ISO 15223-1	5.7.5
	Patient information website	Indicates a website where a patient may obtain additional information on the medical product	ISO 15223-1	5.7.4
	Open Here	To identify the location where the package can be opened and to indicate the method of opening it.	ISO 7000-3079	N. A

Stryker Symbols

Symbol	Title of Symbol	Description of Symbol
	Sterilized using hydrogen peroxide	Indicates a medical device that has been sterilized using hydrogen peroxide.
	Contact by Phone	Indicates an instruction to dial telephone number(s). The symbol is accompanied by the available telephone number(s).
	Open Here	To identify the location where the package can be opened and to indicate the method of opening it.
	QTY	Quantity

English

TRIATHLON TOTAL KNEE SYSTEM

TRIATHLON® REVISION INSERT X3® COMPONENTS

Description

Howmedica Osteonics Corp.'s Triathlon® Revision Insert X3® components of the Triathlon® Total Knee System are designed to be used in total reconstructive replacement of the knee joint. The characteristics specific to each device are detailed on the product label.

Tibial Components: The tibial inserts are available in total stabilizing (TS) design. Tibial inserts are available in a range of thicknesses and are provided with a stabilizer pin and filler bushing subcomponents.

Materials:

The devices are manufactured from materials that meet the following standards:

Triathlon® Revision Insert X3® (5612-X-XXX)

Material Description	Substances in Material	Increments (% w/w)	Material Weight Range (g)	Material Concentration Range (% w/w)
UHMWPE Type 1 (ASTM F648) (ISO 5834-1) (ISO 5834-2) Tibial Insert Body	UHMWPE	100	19.7-89.8	100
Wrought Co-Cr-W-Ni (ASTM F90) Locking Wire	Carbon	0.05 – 0.15	0.117-0.196	48.1-48.5
	Manganese	1.00 – 2.00		
	Silicon	≤0.40		
	Phosphorus	≤0.040		
	Sulfur	≤0.030		
	Chromium	19.00 – 21.00		
	Nickel	9.00 – 11.00		
	Tungsten	14.00 – 16.00		
	Iron	≤3.00		
	Cobalt	46.4 – 57.0	0.126-0.208	46.4-57.0
CoCr Alloy 1 (ASTM F1537) Stabilizer Pin	Carbon	≤0.14	4.09-4.38	31.0-41.1
	Chromium	26.0 – 30.0		
	Molybdenum	5.0 – 7.0		
	Nickel	≤1.0		
	Iron	≤0.75		
	Silicon	≤1.0		
	Manganese	≤1.0		
	Nitrogen	≤0.25		
	Cobalt	58.9 – 69.0	5.86-9.75	58.9 – 69.0
CoCr Alloy 1 (ASTM F1537) Filler Bushing	Carbon	≤0.14	17.1-22.7	31.0 – 41.1
	Chromium	26.0 – 30.0		
	Molybdenum	5.0 – 7.0		
	Nickel	≤1.0		
	Iron	≤0.75		
	Silicon	≤1.0		
	Manganese	≤1.0		
	Nitrogen	≤0.25		
	Cobalt	58.9 – 69.0	32.5-38.1	58.9 – 69.0

Compatibility

Howmedica Osteonics Corp.'s Triathlon® Knee System includes femoral and tibial insert components.

Triathlon® Revision Insert X3 components (5612-X-XXX) are available in sizes 1 through 7 and in various thicknesses. The Inserts can be used with the Triathlon® Revision Tibial Baseplate (5612-B-X00), and Triathlon® TS Femoral component (5512-F-X0Y).

Indications for US and Rest of World

General Total Knee Arthroplasty (TKR) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis, or avascular necrosis), rheumatoid arthritis or post-traumatic arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture-management techniques.

Additional Indications for Total Stabilizer (TS) Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.
- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Indications for Australia

General Primary Knee Arthroplasty (TKA) Indications:

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.

Additional Indications for Total Stabilizer (TS) Components:

- Revision of previous unsuccessful knee replacement or other procedure.

The following indications apply in complex primary and/or revision Total Knee Arthroplasty:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.
- Severe anteroposterior instability of the knee joint.
- Severe instability of the knee secondary to compromised collateral ligament integrity or function.

Refer to the package insert of the devices with which the device listed will be used for a complete list of related indications and contraindications.

Contraindications

- Any active or suspected latent infection in or about the knee joint.
- Distant foci of infection which may cause hematogenous spread to the implant site.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability,

prosthesis fixation failure, or complications in postoperative care.

- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.
- Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function.
- Known or suspected sensitivity and/or allergy to any material in the device.

Warnings

In using this system, the surgeon should be aware of the following:

- In selecting patients for total joint replacements, the following factor is of extreme importance to the eventual success of the procedure: The patient's weight. The heavier the patient, the greater the load on the prosthesis. As the loads on the prosthesis increase, the chance a patient will suffer adverse reactions increases, including but not limited to failure of fixation, loosening, fracture and dislocation of the device and can lead to a decreased service life. The effect of these loads will be accentuated when a small sized prosthesis is used in larger patients. Overweight or obese patients impose greater loads on the prosthesis. As obesity is a clinical diagnosis, we leave it to the surgeon to make the diagnosis based on his/her own clinical judgment. However, the World Health Organization (WHO) defines "overweight" as a BMI equal to or more than 25, and "obesity" as a BMI equal to or more than 30.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.
- Polished bearing areas must not come in contact with hard or abrasive surfaces.
- Bearing areas must always be clean and free of debris prior to assembly.
- Contouring or bending of an implant may reduce its fatigue strength and cause failure under load.
- The metal retaining wire on the insert should not be handled or removed, as it is critical to the security of the assembly. Discard any tibial bearing insert if the metal retaining wire appears damaged or mishandled. Tampering with this assembly can result in improper function of the retaining mechanism.
- Use caution when handling any sharp-edged orthopedic device
- Except where noted, Howmedica Osteonics Corp. strongly advises against the use of another manufacturer's total knee component with any of Howmedica Osteonics' total knee components. Any such use will negate the responsibility of Howmedica Osteonics Corp. for the performance of the resulting mixed component implant.
- Intentional removal of a total knee component can be accomplished by careful use of cutting burs, thin and narrow osteotomes and cautious extraction forces.
- Intentional removal of the plastic tibial insert after its assembly into the metal baseplate results in the destruction of the plastic insert. Care should be taken not to nick or notch the surface of the tibial baseplate during insert removal.
- Return all packages with flaws in the sterile barrier to the supplier. **Do not resterilize.**
- Components labeled for "Cemented Use Only" are to be implanted only with bone cement.
- **Patient post-operative pain**. Inherent to all joint replacement is the risk that a patient will develop postoperative pain; pain is a commonly reported symptom regardless of the device implanted. The clinical literature reveals numerous potential causes of pain not directly related to the implant performance including, but not limited to, prior history of trauma and natural disease progression.
- For patients who present with pain following implantation of any orthopedic implant system, the physician should consider all potential causes of the symptoms identified in the clinical literature, including infection, soft tissue impingement, and possible adverse local tissue reactions associated with wear debris, metal ions or corrosion. Accurate diagnosis of the source of pain and directed, timely intervention is essential to ensuring effective treatment of pain.
- This is a single-use device and should never be reused. Reuse of a single-use device may result in a

myriad of risks including, but not limited to:

1. Contaminants leading to infection
2. Material fragments, debris, corrosion byproducts or unintended foreign objects leading to inflammatory response
3. Biologic Contaminants (non-pathological) leading to inflammation.

Additionally, although the device may appear undamaged, previous use may have created nonvisible damage that could result in loss of device functionality such as:

1. Fractured device
2. Assembly issues

- See the "Information for Patients" Section for more information.
- The Triathlon® Revision Insert X3 devices contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight:
    1. Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

  Current scientific evidence supports that medical device manufactured from cobalt alloys or stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. Refer to the listed device label to determine if the device contains hazardous substances.

Precautions

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device.
- Surgeons must advise patients of both the limitations of the reconstruction and the need for protection of the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated in failure of the reconstruction by loosening, fracture and/or wear of the prosthetic implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
- Surgeons should caution patients to limit activities and protect the replaced joint from unreasonable stresses and to follow the instructions of the physician with respect to follow-up care and treatment.
- Surgeons should warn patients of potential adverse effects, including the finite service life of the device and the need for post-operative protection of the implant. The surgeon should warn patients that the device does not replicate the flexibility, strength, reliability, or durability of a normal healthy joint and that the implant can break or become damaged as a result of strenuous activity or trauma.
- Appropriate selection, placement and fixation of the total knee components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biological, biomechanical and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
- Surgeons should warn patients with metallic implants of the potential risks of undergoing a Magnetic Resonance Imaging (MRI) scan. The electromagnetic field created by an MRI scanner can interact with the metallic implant, resulting in displacement of the implant, heating of the tissue near the implant, implant damage or malfunction, or other undesirable effects. In addition, the presence of a metallic implant can produce an image artifact that may appear as a void region or geometric distortion of the true image. If the image artifact is near the area of interest, it may make the MRI scan uninformative or may lead to inaccurate clinical diagnosis or treatment.

Magnetic Resonance Imaging (MRI) Safety Information

The Triathlon® Revision Insert X3® Components of the Triathlon® Total Knee System have been evaluated for safety and compatibility in the MR environment.

Non-clinical testing demonstrated that the devices listed are MR Conditional. A patient with the listed devices can be safely scanned in an MR scanner under the following conditions. Failure to follow these conditions may result in injury:

Device Name	Triathlon® Revision Insert X3® Components
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	3000 Gauss/cm (30 T/m)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole Body
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	0.5 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)
Scan Duration	Patients can be scanned at 0.5 W/kg whole-body average SAR for 12 minutes, followed by 18 minutes of wait time. This sequence can be repeated twice in 60 minutes. Under the scanning conditions and sequence defined above, these devices are expected to produce a temperature rise of less than 6.0 °C.
MR Image Artifact	The presence of this implant may produce an image artifact. In nonclinical testing, the image artifact caused by the device extends approximately 113 mm from the device when imaged with a gradient echo or spin echo pulse sequence using a 3.0 T/128 MHz MR system.

Adverse Effects

- While the expected life of total knee replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical, and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone. Surgeons should counsel patients against having unrealistic expectations about the lifetime of the device.
- Dislocation of the femoral, tibial, or patellar prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.
- Loosening of total knee components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis, component malalignment or trauma. Late loosening may result from trauma, infection, biological complications including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Fatigue fracture of total knee components, including tibial, femoral and patellar components, has

occurred in a small percentage of cases. Knee component fracture may result due to inadequate support of the component by the underlying bone or poor component fixation.

- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- Serious complications may be associated with any total joint replacement surgery. These complications include but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Wear of polyethylene components has occurred and literature reports have associated its occurrence with bone resorption, loosening and infection.
- Although rare, sensitivity/allergic reactions to the materials in the implant have occurred in patients following joint replacement. Implantation of foreign material in tissues can result in immune responses and in histological reactions involving macrophages and fibroblasts.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint and/or amputation of the limb.
- Soft tissue imbalance and/or laxity has been related to component malalignment, which may result in early wear and/or failure of the implant.
- Polyethylene particles and metal particles from mechanisms other than wear. Very small particles from metal and polyethylene components can be shed from non-articulating surfaces during normal use and over time. Although most of these particles stay in the relevant joint (i.e. contained in the synovium) or are trapped by surrounding scar tissue, microscopic particles can migrate throughout the body and on occasions have been described as accumulating in lymph nodes and other parts of the body. Although no significant medical complications have been reported as a result of these particles, their migration and/or accumulation in the body have been described in the literature. The long-term effects, if any, from these particles, are unknown. The long-term effects have been theorized to include:
    - Cancer: There is presently no scientific evidence that links metallic or polyethylene debris with cancer. However, the possibility cannot be ruled out.
    - Lymphadenopathy and Accumulation in Other Tissues/Organs: There have been a few reports of the accumulation of wear debris in lymph nodes (proximate and distal). Although no medical complications or disease processes have been reported as stemming from these accumulations, their existence should be recognized to facilitate diagnosis and avoid confusion with suspicious lesions, cancerous or otherwise.
    - Systemic Disease: There has been some speculation that there could be an association between migration of debris and as yet unspecified systemic effects. It is possible that some long-term effects may be demonstrated at some point in the future, but because there is very little scientific data suggesting association between migration of debris and systemic disease, it is believed that the benefits of these devices clearly outweigh the potential risks for any such theoretical long-term effect.

In case of serious incident, please notify the Manufacturer and Competent Authority in your region.

Information for patients

- The surgeon must warn patients of surgical risks and inform them of possible adverse effects. The surgeon must warn patients that the implant does not replicate the flexibility, strength, reliability, or durability of a normal healthy joint, that the implant can break or become damaged for numerous reasons, including as a result of strenuous activity or trauma, and that the implant has a finite service life and may need to be replaced in the future.
- The surgeon must warn patients of the limitations of the reconstruction and the need to protect the implant from full weight bearing until adequate fixation and healing have occurred. The surgeon must

advise the patient to limit activities and protect the implant from strenuous activity, trauma or impact loading, and to follow the surgeon's instructions regarding activity level, follow-up care, and treatment.

- The surgeon must advise patients that the implant cannot be expected to withstand the same activity levels and loads as a normal healthy joint, and that the implant will not restore function to the level expected with normal healthy bone. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the implant, or both. The surgeon must advise the patient against having unrealistic functional expectations.
- The surgeon must warn patients that strenuous activity, trauma or impact loading affecting the implant have been implicated in failure of the implant by loosening, fracture and/or wear of the implants. Many factors, including loosening of the implant components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
- Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other surgical procedures have also been associated with transient bacteremia. To help minimize the risk of infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures. Surgeons should advise the patient to inform their doctors/dentists if they have an artificial joint replacement so that a decision can be made regarding antibiotic prophylaxis for such procedures.
- Additional information for the patient can be found here: patientinfo.stryker.com

How Supplied

- This total knee component has been sterilized by gamma radiation, hydrogen peroxide gas plasma, or ethylene oxide. Refer to the package label for the sterilization method.
- Do NOT resterilize.
- Inspect the packaging of sterile products for flaws before opening. In the presence of any flaws, assume that the product is not sterile.
- Use caution to prevent contamination of any components.
- Discard ALL nonsterile or contaminated products.
- Device should not be used after the expiry date displayed on the label as packaging has not been validated beyond this date.
- Single use devices cannot be explanted and subsequently reimplanted as the physical forces exerted by these actions may compromise the physical integrity, dimensions and/or surface finishes of the devices. Also, sterility cannot be assured for reused devices as cleaning and re-sterilization procedures have not been verified.

Transport & Storage Information

The device is individually packed in protective packaging that is labelled according to its contents. Store and transport the device in the original protective packaging. Do not remove the device from the packaging until it is planned to be used. Store the device in standard hospital environmental conditions unless specific requirements are defined and described on the product label.

Use and Implantation

- Use the recommended trial components for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- Care should be taken to remove bone chips, bone cement fragments and metallic debris from the implant site to reduce the risk of debris induced accelerated wear of the articular surfaces of the implant.
- Howmedica Osteonics Corp.'s Surgical Protocols provide additional procedural information.

Consult the product label for specific product compatibility.

Clinical Benefits/Clinical Performance Data

The clinical benefits of the Triathlon® Total Knee System include decreased pain and increased function. These claims are supported by a review of the clinical data for the Rotating Hinge Knee System obtained from one or more of the following sources: national joint replacement registries, clinical studies, and/or a review of the clinical literature. These data, in conjunction with supporting bench-top test data and engineering analyses, substantiate that the device performs as intended and remains state of the art for the indications listed.

The expected lifetime of the device is based upon non-clinical testing models that were designed to meet a minimum of at least 10 years of simulated use. Patient factors such as weight, bone quality, activity level and other medical conditions and comorbidities may increase or decrease the expected lifetime of this or any implantable orthopedic device.

Safe Disposal

If a device is being returned for evaluation, please contact your local Stryker representative for shipping/handling information. If the device is not being returned to Stryker, implant components are to be disposed of in accordance with applicable laws, rules, and regulations for the disposal of biohazardous waste. Follow all guidelines for biohazardous waste in accordance with the Centers for Disease Control and Prevention guidelines as well as applicable federal/national, state and local regulations. As part of the disposal process, verify that the implant in its entirety has been explanted from the surgical site.

List of abbreviations used in labelling

Term	Abbreviation	Term	Abbreviation
Alpha Code	ALPH CDE	Neck	NK
Angle	ANG	Offset	OFFST
Degree	DEG or °	Outer Diameter	OD
Depth	DPTH	Right	RT ►
Diameter	DIA	Screw Holes	SCR HLS
Distal	DSTL	Side	SDE
Extra Deep	XDP	Size	SZE
Extra Large	XLGE	Small	SM
Extra Small	XSM	Standard	STD
Head	HD	Stem	STM
Height	HT	Taper	TPR
Inner Diameter	ID	Thickness	THKNS
Insert	INSR	Type	TYP
Large	LGE	Width	WDTH
Left	◄ LFT	With	W/
Length	LNTH	Without	W/O
Medium	MED		

CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

CE Disclaimer
Refer to product label for CE Mark Status and Legal Manufacturer. The CE mark is only valid if also found on the product label.

Trademark Statement
Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks: Howmedica, Osteonics, Stryker, and Triathlon. All other trademarks or service marks are trademarks and service marks of their respective owners or holders.

Patient Implant Card Instructions (for Health Care Professionals)
Healthcare providers are responsible for completing the following information on the provided Patient Implant Card. Once complete, that Patient Implant Card should be given to the patient.

- Name of the patient
- Date of implantation
- Name and address of surgical centre
- Type of implant in native language